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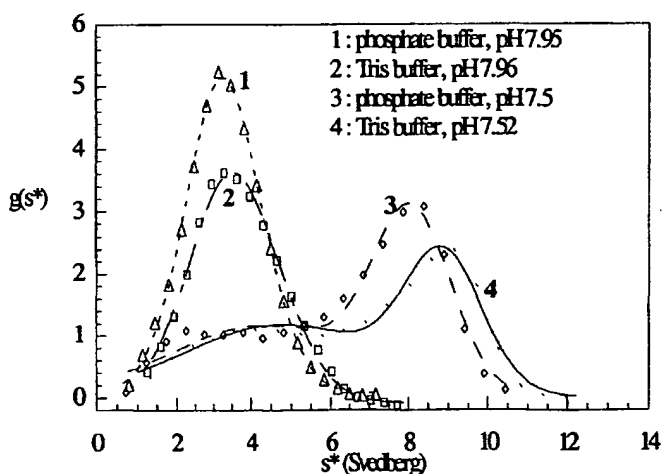
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(54) Title: MONODISPERSE HEXAMERIC ACYLATED INSULIN ANALOG FORMULATIONS



(57) Abstract: The present invention provides formulations and methods for preparing formulations containing an aqueous solution at a pH of greater than about 7.9. The aqueous solution includes an isotonicity agent, a phenolic derivative, zinc ions, and an acylated human insulin analog. More particularly, the invention relates to formulations having a pH of greater than about 7.9 that include a monoacylated human insulin analog such as an acylated des(B30) human insulin analog or an analog that comprises a native or modified human insulin A chain optionally modified at position A21, and a modified native human insulin B chain optionally modified at position B3 and modified at position B28, or at both positions B28 and B29, and that contains a lysine residue at either position B28 or B29 acylated with a fatty acid residue. The invention also provides a method for treating a patient suffering from hyperglycemia using the pharmaceutical formulations of the invention.



— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

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A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 48414 A (NOVO NORDISK) 24 December 1997 (1997-12-24) claims 1-18 page 5, line 5 - line 13 page 6, line 1 - line 3 ---	1-59
P, X	WO 99 34821 A (NOVO NORDISK) 15 July 1999 (1999-07-15) claims 1-14 page 9; example 1 ---	1-59
A	WO 98 34953 A (NOVO NORDISK) 13 August 1998 (1998-08-13) the whole document -----	1-59

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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